

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ALEXANDRA PERCIBALLI and LEWIS	:
PERCIBALLI,	:
Plaintiffs,	: <u>MEMORANDUM</u>
	: <u>DECISION AND ORDER</u>
- against -	: 20-CV-5178 (AMD) (RER)
ETHICON, INC., ETHICON LLC, and	:
JOHNSON & JOHNSON,	:
Defendants.	:
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ANN M. DONNELLY, United States District Judge:

On April 15, 2013, the plaintiffs brought this action via short-form complaint as a part of a multidistrict litigation (“MDL”), *In re: Ethicon, Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327 (S.D. W. Va.). The plaintiffs in that litigation claim that they were harmed by the implantation of various polypropylene-based mesh products, including tension-free vaginal tape (“TVT”). The defendants moved for summary judgment on May 9, 2019 (ECF No. 47) and the case was transferred to this Court on October 27, 2020 (ECF No. 78). I heard oral argument on January 14, 2021 and the parties submitted supplemental briefing on the statute of limitations issue on January 28, 2021. (ECF Nos. 89, 90.) For the reasons set forth below, the defendants’ motion is granted.

BACKGROUND

As early as June of 2000, Andrea Perciballi experienced “leaking urine;” her bladder control problems worsened over time. (ECF No. 47-1 at 38 (Ex. B Dep. Tr. 107:12-15, 108:11-15).) She wore protective pads to work, occasionally leaked urine during sexual intercourse, and

had some “right abdominal pain.” (*Id.* at 38, 40 (Ex. B Dep. Tr. 106:22-107:1, 114:8-17); ECF No. 62-4 (Ex. D).) Her doctor, Dr. Harvey Winkler of Manhasset, New York, diagnosed stress urinary incontinence and a fallen bladder. He “highly recommended” the TVT implant to alleviate Ms. Perciballi’s symptoms. (ECF No. 47-1 at 42 (Ex. B Dep. Tr. 124:4-8).) On July 2, 2002, Dr. Winkler implanted TVT to treat Ms. Perciballi’s condition. (ECF No. 1 at 4; ECF No. 47-1 at 4 (Ex. A).)

However, complications arose soon after Dr. Winkler implanted the device. In a fact sheet that she filled out under oath as part of the MDL, Ms. Perciballi wrote that she started experiencing symptoms specifically related to the TVT in “mid to late 2003,” including “severe vaginal and pelvic pain, irritation, infections, incontinence, constant urgency, difficulties with intercourse and loss of sleep due to incontinence . . . recurrent UTIs, loss of bladder control, fallen bladder, erosion from mesh into bone, muscles and nerves . . . heavy bodily scarring as well as psychological scarring from marital issues.” (ECF No. 47-1 at 6 (Ex. A).) She attributed these symptoms to the TVT, and wrote that her pain “progressively got worse” over time.¹ (*Id.*) Between 2003 and 2006, Ms. Perciballi experienced worsening urinary incontinence, severe pain and dyspareunia. (ECF No. 47-1 at 46-52 (Ex. B Dep. Tr. 140:22-141:23, 151:1-2, 165:4-8).)

Ms. Perciballi was “hoping that [she would] get better” and was “in denial” about whether the TVT had worked. (*Id.* at 49 (Ex B Dep. Tr. 151:6-9).) In 2006, Ms. Perciballi sought treatment from Dr. Yael Fuchs, an OBGYN, who referred her to Dr. Marisa Mastropietro, a urogynecologist. (ECF No. 62-2 at 2.) According to Ms. Perciballi, the doctors told her that the

¹ At her deposition, Ms. Perciballi testified that she had been “experiencing symptoms since 2005.” (ECF No. 47-1 at 20 (Ex. B Dep. Tr. 34:22-23).)

TVT sling “needed” to be “repaired” and was causing her “pain with sexual relations.”² (ECF No. 47-1 at 48 (ECF No. 47-1 at 26, 48-49 (Ex. B Dep. Tr. 58:4-59:6, 149:2-150:5).) Dr. Fuchs “thought repairing the sling would help with [her] pain complaints.” (*Id.* at 49 (Ex. B. Dep. Tr. 150:2-5.)

In her medical records, Dr. Mastropietro observed that Ms. Perciballi had “recurrent complaints of stressed urinary incontinence with urge and urge incontinence, along with pelvic pressure.” (ECF No. 62-2 at 2.) In a May 18, 2006 letter to Dr. Fuchs, Dr. Mastropietro noted that Ms. Perciballi’s 2002 implant resolved her pre-TVT symptoms temporarily, but that she complained of worsening urinary symptoms “in the last 1-2 years,” as well as increased pelvic organ prolapse symptoms and painful intercourse. (ECF No. 47-1 at 91 (Ex. D).) On June 26, 2006, Dr. Mastropietro and Dr. Fuchs performed surgery on Ms. Perciballi; Dr. Mastropietro implanted a second TVT device in an effort to ease Ms. Perciballi’s symptoms, and Dr. Fuchs did a complete hysterectomy.³ (ECF No. 1 at 4; ECF No. 47-1 at 33, 48 (Ex. B Dep. Tr. 89:8-16, 148:13-16).)

After the second surgery, Ms. Perciballi’s pain subsided only “for a time period.” (ECF No. 47-1 at 53 (Ex. B Dep. Tr. 169:14).) During a follow-up visit with Dr. Mastropietro on May 17, 2007, Ms. Perciballi reported that she was experiencing occasional right groin pain. (ECF No. 47-1 at 146 (Ex. E Dep. Tr. 174:23-175:9).) She had multiple follow-up visits with Dr. Fuchs: in October of 2006, she complained of “pelvic pain;” in May of 2007 she complained of

² Dr. Mastropietro testified at her deposition that she had no recollection of Ms. Perciballi’s surgery, and relied on her records, which do not include any mention of the TVT as the cause of the plaintiff’s symptoms. (ECF No. 47-1 at 136 (Ex. E Tr. 134:13-18).)

³ Ms. Perciballi testified at her deposition that she told the doctor that she “did not want another mesh” and that she thought that Dr. Mastropietro was going to “repair” the TVT. In addition, she thought Dr. Fuchs was going to do a partial hysterectomy. (ECF No. 47-1 at 33 (Ex. B Dep. Tr. 88:23-89:19, 156:12-157:13).)

“urinary frequency . . . and occasional right groin pain;” and in October of 2007 she complained of “co pelvic pain.” (ECF No. 62-18 at 10-11.) In March of 2010, Ms. Perciballi had an abdominal and pelvic ultrasound for “abdominal pain and distention” and “post partial hysterectomy for uterine prolapse.” (*Id.*) She saw Dr. Fuchs again in early 2011 and reported “frequency/dysuria” and “pain in vagina.” (*Id.* at 12.) At her next appointment with Dr. Mastropietro in March of 2011, Ms. Perciballi complained of lower abdominal and groin pain, urinary incontinence and dyspareunia. (ECF No. 47-1 at 92-93 (Ex. D).)

Dr. Daniel S. Elliott, a medical expert retained by the plaintiffs to assess Ms. Perciballi’s record, opined that the TVT caused Ms. Perciballi’s vaginal pain, pelvic pain and dyspareunia. He did not differentiate between the 2002 and 2006 procedures, but said she had “new complaints” after the surgery including “frequent urination and lower quadrant pain.” (ECF No. 47-1 at 91 (Ex. D).)

Ms. Perciballi linked her symptoms to the TVT implant after she and her husband read a Consumer Reports article in May of 2012; she told him, “Look . . . there is my problem right there. All my complaints are right there.” (ECF No. 47-1 at 19 (Ex. B Dep. Tr. 30:15-21).) Dr. Anne Hardart, who started treating Ms. Perciballi in March of 2013, confirmed that Ms. Perciballi’s symptoms—recurrent urinary tract infections, pelvic and vaginal pain and mixed urinary incontinence—were caused by TVT. (ECF No. 47-1 at 6 (Ex. A); ECF No. 62-11 at 2-3.) On August 6, 2014, Dr. Hardart removed part of Ms. Perciballi’s TVT. (ECF No. 47-1 at 5 (Ex. A); ECF No. 62-11 at 2.) Dr. Shlomo Raz removed the remaining TVT on March 2, 2018 after Ms. Perciballi continued to complain of recurrent urinary tract infections, vaginal bleeding, dyspareunia and other symptoms. (ECF No. 62-14 at 2.)

Before the implants were removed, Ms. Perciballi filed suit in the MDL proceeding, alleging the following state law claims arising from the 2002 and 2006 TVT procedures:

Count I: Negligence

Count II: Strict liability – Manufacturing Defect

Count III: Strict Liability – Failure to Warn

Count IV: Strict Liability – Defective Product

Count V: Strict Liability – Design Defect

Count VI: Common Law Fraud

Count VII: Fraudulent Concealment

Count VIII: Constructive Fraud

Count IX: Negligent Misrepresentation

Count X: Negligent Infliction of Emotional Distress

Count XI: Breach of Express Warranty

Count XII: Breach of Implied Warranty

Count XIII: Violation of Consumer Protection Laws

Count XIV: Gross Negligence

Count XV: Unjust Enrichment

Count XVI: Loss of Consortium

Count XVII: Punitive Damages

Count XVIII: Discovery Rule and Tolling

(ECF No. 1 at 4-5.)

The plaintiffs have withdrawn the following claims: strict liability – manufacturing defect (Count II), strict liability – failure to warn with respect to the 2006 TVT implant (Count III),

strict liability – defective product (Count IV), common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), negligent infliction of emotional distress (Count X), breach of express warranty (Count XI), breach of implied warranty (Count XII), violation of consumer protection laws (Count XII), and unjust enrichment (Count XV).⁴ (ECF No. 62.)

Thus, the remaining claims before the Court are negligence as to the 2002 and 2006 TVT implants (Count I), strict liability – design defect as to the 2002 and 2006 TVT implants (Count V), gross negligence as to the 2002 and 2006 TVT implants (Count XIV), failure to warn as to the 2002 TVT implant (Count III), and the derivative claim of loss of consortium (Count XVI). The defendants argue that all of the remaining claims should be dismissed on statute of limitations grounds. In the alternative, the defendants move for summary judgment on the merits on Counts I, III and XIV only as to the 2006 TVT implant and on Count V as to both the 2002 and 2006 TVT implant.

STANDARD OF REVIEW

Summary judgment is appropriate only if the parties' submissions, including deposition transcripts, affidavits or other documentation, show that there is "no genuine dispute as to any material fact," and the movant is "entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). The movant has the burden of showing the absence of any genuine dispute as to a material fact. *McLee v. Chrysler Corp.*, 109 F.3d 130, 134 (2d Cir. 1997) (citation omitted). A fact is "material" when it "might affect the outcome of the suit under the governing law," and an issue of fact is "genuine" if "the

⁴ The plaintiffs have also reserved their right to oppose dismissal on the merits as to Counts I, III and XIV with respect to the 2002 TVT implant should the defendants seek supplemental summary judgment briefing on those claims. The plaintiffs' claims for punitive damages (Count XVII) and "discovery rule and tolling" (Count XVIII) are not independent causes of action.

evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Barlow v. Male Geneva Police Officer Who Arrested Me on Jan. 2005*, 434 F. App’x 22, 25 (2d Cir. 2011) (internal citations omitted). Once the moving party has met its burden, the party opposing summary judgment must identify specific facts and affirmative evidence that contradict those offered by the moving party to demonstrate that there is a genuine issue for trial. *Ethelberth v. Choice Sec. Co.*, 91 F. Supp. 3d 339, 349 (E.D.N.Y. 2015) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 324 (1986)).

DISCUSSION

I. Statute of Limitations

The plaintiffs’ remaining claims are subject to New York’s three-year statute of limitations.⁵ See N.Y. C.P.L.R. § 214(5) (providing three-year statute of limitation for “an action to recover damages for a personal injury” subject to certain exceptions). This period begins to run “when the product first injured the plaintiff.” *Kwas v. Intergraph Gov’t Sols.*, 2016 WL 4502039, at *2 (E.D.N.Y. Aug. 24, 2016) (citing *New York Seven-Up Bottling Co. v. Dow Chem. Co.*, 466 N.Y.S.2d 478, 479-80 (1983)); see also *Victorson v. Bock Laundry Mach. Co.*, 37 N.Y.2d 395, 399-400 (1975) (under C.P.L.R. § 214(5), New York’s statute of limitations for strict products liability claims is three years and begins to run on the date of injury). This is true “even if the plaintiff is unaware that he or she has a cause of action” at the time of injury. *Woodlaurel, Inc. v. Wittman*, 199 A.D.2d 497, 498 (N.Y. App. Div. 1993). “The rationale is that the injury puts the putative plaintiff on inquiry notice, and therefore, charges him or her with responsibility for investigating, within the limitations period, all potential claims and all potential

⁵ The parties agree that New York law applies to the plaintiffs’ claims. (ECF No. 48 at 5; ECF No. 62 at 5.)

defendants.” *Zimmerman v. Poly Prep Country Day Sch.*, 888 F. Supp. 2d 317, 337 (E.D.N.Y. 2012) (internal quotation marks and citations omitted).

“In cases involving the malfunction of medical devices ‘implanted or inserted into the human body,’ the statute of limitations ‘runs from the date of the injury resulting from the malfunction.’” *Baker v. Stryker Corp.*, 770 F. App’x 12, 14 (2d Cir. 2019) (quoting *Martin v. Edwards Labs.*, 60 N.Y.2d 417, 422 (1983)). “In other words, the ‘three year limitations period runs from the date when plaintiff first noticed symptoms, rather than when a physician first diagnosed those symptoms.’” *Id.* (quoting *Galletta v. Stryker Corp.*, 283 F.Supp.2d 914, 917 (S.D.N.Y. 2003)).

Ms. Perciballi filed this action on April 15, 2013. Thus, for her claims “to be timely under New York’s three-year statute of limitations, [she] must have experienced an injury caused by the claimed defect no earlier than” April 15, 2010. *Baker v. Porex Corp.*, 2018 WL 1440311, at *5 (E.D.N.Y. Mar. 22, 2018), *aff’d sub nom. Baker v. Stryker*, 770 F. App’x 12 (citing *Guisto v. Stryker Corp.*, 293 F.R.D. 132, 136 (E.D.N.Y. 2013) (“If [the plaintiff] is able to avoid the applicable three-year statute, any of the continuous pain [the plaintiff] felt before this cutoff date could not have been caused by, or traceable to . . . the claimed defect.”)). The record shows that Ms. Perciballi was aware of her alleged injuries nearly ten years before filing her claim. First, in connection with the filing of this lawsuit, she completed a fact sheet in which she was asked, “When is the first time you experienced symptoms of any of the bodily injuries you claim in your lawsuit to have resulted from the pelvic mesh product(s)?” (ECF No. 47-1 at 6.) She answered, “Mid to late 2003, pain progressively got worse.” (*Id.*) The form also instructed her to “describe the bodily injuries . . . that you claim resulted from the implantation of the pelvic mesh product(s).” (*Id.*) Ms. Perciballi wrote: “Following the implant I experienced severe

vaginal and pelvic pain, irritation, infections, incontinence, constant urgency, difficulties with intercourse and loss of sleep due to incontinence. In addition, I also experienced recurrent UTIs, loss of bladder control, fallen bladder, erosion from mesh into bone, muscles and nerves. As well as heavily bodily scarring as well as psychological scarring from marital issues.” (*Id.*)

By 2006, Ms. Perciballi was experiencing pain, incontinence and dyspareunia. She testified that Dr. Fuchs and Dr. Mastropietro linked her symptoms to the 2002 implant, and told her that the implant needed to be “repaired.”⁶ Dr. Mastropietro implanted a second TVT device, which alleviated her symptoms for a short time. In 2007, Ms. Perciballi again sought treatment for pelvic pain and more frequent urination. Ms. Perciballi had a portion of TVT removed in 2014 because of recurrent urinary tract infections, pelvic and vaginal pain and incontinence; it is not apparent from the record whether Dr. Hardart removed the 2002 or 2006 implant, nor whether it was possible to differentiate between the two. (ECF No. 62-11 at 2.) Dr. Elliott, the plaintiffs’ expert, attributed Ms. Perciballi’s symptoms to both TVT implants. (ECF No. 47-1 at 98 (Ex. D).) Thus, based on the record and deposition testimony, Ms. Perciballi’s TVT symptoms began in 2003, worsened over time, and were not resolved by the second implant in 2006.⁷

In *Martin v. Edward Labs*, the court held that “the proper rule to be applied with respect to products implanted or inserted in the human body is neither the time of implantation or insertion nor time of discovery, but . . . the date the product malfunctions.” *Martin v. Edwards*

⁶ As explained earlier, Dr. Mastropietro had no independent recollection of the surgery, and her records do not reflect this conversation.

⁷ The plaintiffs’ expert did not specify whether one or both devices caused Ms. Perciballi’s symptoms, and the plaintiff does not suggest that it is possible to make that determination. After the 2006 implant, Ms. Perciballi complained of pain and other symptoms as early as 2007. The record does not indicate that there is any way to differentiate as between the implants, and these symptoms began long before April of 2010.

Labs., Div. of Am. Hosp. Supply Corp., 60 N.Y.2d 417, 428, 457 N.E.2d 1150 (1983). The plaintiffs say that the TVT did not “malfunction” until 2013, when Ms. Perciballi learned from Dr. Hardart that the TVT caused her symptoms. (ECF No. 89.) According to the plaintiffs, because the defendants cannot “prove” the TVT devices malfunctioned until 2013, the statute of limitations did not start to run until then. (ECF No. 89 at 3.)

The plaintiffs distinguish *Baker*, in which the Second Circuit cited *Martin v. Edward Labs* for the proposition that the statute of limitations begins to run when the plaintiff notices the symptoms, not when the malfunction is diagnosed. 770 F. App’x 12, 14 (2d Cir. 2019). In affirming the district court’s grant of summary judgment on statute of limitations grounds, the court agreed that “Baker’s injury occurred on or around August 22, 2006—the date the devices were implanted, causing pain almost immediately thereafter—and that Baker’s personal injury claims, for statute of limitations purposes, accrued on that date.” *Id.* at 15.

The plaintiffs say that *Baker* is different, because Baker “immediately felt intense and ‘radically different’ pain and choking sensations alleged to be ‘sole[ly]’ caused by” the medical device implant. (ECF No. 89 at 1 (quoting *Baker v. Stryker*, 770 F. App’x at 12).) By contrast, the plaintiffs argue, Ms. Perciballi’s symptoms were not sufficiently different from her pre-implant symptoms so that she could attribute them to the TVT. The record does not support the plaintiff’s claim. It was primarily incontinence that led Ms. Perciballi to seek treatment.⁸ But after the implants, Ms. Perciballi had different symptoms—including severe vaginal and pelvic pain, irritation, infections, constant urgency, recurrent UTIs, loss of bladder control, and fallen bladder—that intensified over time. As she stated in the fact sheet, she first experienced symptoms in “[m]id to late 2003.” These symptoms, which she enumerated in the fact sheet,

⁸ Ms. Perciballi also had some right abdominal pain.

were different than her pre-implant symptoms and she attributed them to the TVT. She also testified that she “was experiencing symptoms since 2005.”⁹ (ECF No. 47-1 at 20 (Ex. B Dep. Tr. 34:22-23).) It is ““discovery of the physical condition and not . . . the more complex concept of discovery of both the condition and the nonorganic etiology of that condition”” that starts the statute of limitations clock. *See Ferreri v. McGhan Med. Corp.*, 1997 WL 580714, at *3 (S.D.N.Y. Sept. 17, 1997) (quoting *Wetherill v. Eli Lilly & Co.*, 655 N.Y.S.2d 862, 866 (1997)).

By her own account, Ms. Perciballi “first noticed” the symptoms in 2003; the fact that she did not learn the cause of these symptoms until 2013 is immaterial.¹⁰ *See Guisto*, 293 F.R.D. at 137 (“The allegation that plaintiffs only learned of the device’s lack of ingrowth and fixation in March 2011 is immaterial; they were aware of the pain that flowed, allegedly, from the defect even if they did not know its source.”); *see also Wetherill*, 655 N.Y.S.2d at 866 (if the statute began to run when the plaintiff discovered the correct diagnosis, “the date for commencing an action under [C.P.L.R. § 214] would depend on such fortuitous circumstances as the medical sophistication of the individual plaintiff and the diagnostic acuity of his or her chosen physician”).¹¹

⁹ Her expert, Dr. Elliott, described some of the symptoms as “new complaints.” (ECF No. 47-1 at 91 (Ex. D).)

¹⁰ Notably, the plaintiffs do not allege that Ms. Perciballi began experiencing any *new* symptoms in 2013, only that Dr. Hardart connected her symptoms to the TVT. Thus, either her pre-2013 symptoms were caused by the TVT, or the TVT was not malfunctioning.

¹¹ The parties agree that the “toxic tort exception” to C.P.L.R. § 214 does not apply. The plaintiff suggested at oral argument that *Baker v. Stryker* was a toxic tort exception case. It was not. Like Ms. Perciballi, Baker argued that “he could not have discovered the cause of his injury” until he had a medical diagnosis,” and, thus, the statute of limitations should have been tolled under the toxic tort exception until the date his injury was discovered. *Baker*, 770 F. App’x at 15. The Second Circuit rejected that argument because “[g]overning case law holds that Baker’s injury does not arise from latent exposure to a substance within the meaning of § 214-c and, therefore, this provision does not save his claim.” *Id.* The same is true here. Ms. Perciballi’s injury does not arise from a toxic tort; thus, the statute of limitations began to run when Ms. Perciballi first noticed her symptoms, not when her symptoms were diagnosed.

The plaintiffs did not file this suit until almost ten years after Ms. Perciballi began experiencing symptoms from the TVT. Accordingly, the claims are time-barred.

II. Derivative Claim

As the plaintiffs concede, Mr. Perciballi's loss of consortium claim is derivative of Ms. Perciballi's claims for relief. *Murphy v. Cadillac Rubber & Plastics, Inc.*, 946 F.Supp. 1108, 1124-125 (W.D.N.Y.1996) ("Loss of consortium is not, in and of itself, a basis for a claim, but is derivative of a tort cause of action") (citing *Millington v. Southeastern Elevator Co.*, 239 N.E.2d 897 (N.Y. 1968)). Because the defendants are not liable on the underlying claims, Mr. Perciballi's loss of consortium claim must also be dismissed. *See Smith v. Herman Miller, Inc.*, 2005 WL 3501883, at *3 (E.D.N.Y. Dec. 21, 2005) ("A loss of consortium claim is a derivative claim, and is thus, not cognizable unless the defendant is liable to the injured spouse." (internal quotations and citation omitted)); *Vega-Santana v. Nat'l R.R. Passenger Corp.*, 956 F. Supp. 2d 556, 562 (S.D.N.Y. 2013) (dismissing derivative claim for loss of consortium because "[w]here the primary cause of action is dismissed on summary judgment, the loss of consortium claim must be dismissed as well.").

CONCLUSION

For the reasons set forth above, the defendants' motion for summary judgment is granted. The Clerk of Court is respectfully directed to enter judgment in favor of the defendants and close the case.

SO ORDERED.

s/Ann M. Donnelly

ANN M. DONNELLY
United States District Judge

Dated: Brooklyn, New York
March 3, 2021